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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SWARTZ, RODNEY P	

ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
05/01/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/590,657	MOLLENHAUER ET AL.	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-66* is/are rejected.

7)☒ Claim(s) *33,45,52 and 58* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 August 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' Response to Restriction Requirement, received 6 November 2008, is acknowledged. Claims 62, 63, 65 and 66 have been amended.

Applicants elect Invention I, claims 31-39 and 61-63, drawn to method of treating disease, with traverse. The traversal is on the grounds that the various inventions do share a special technical feature, i.e., DMPT1 polypeptide or nucleic acid, in various methods.

The examiner has considered applicants' argument, and finds it persuasive.

THE RESTRICTION REQUIREMENT IS HEREBY VACATED.

2. Claims 31-66 are pending and under consideration.

Specification

3. The disclosure is objected to because of the following informalities:

Page 1, line 36, delete one of the ending parentheses following SEQ ID NO:1.

Page 2, line 32, what is meant by "found that a by 40%"?

Page 8, lines 8-24, all names of bacteria should be in italics to be consistent with the rest of the specification.

Appropriate correction is required.

Drawings

4. Figures 1-11 are objected to because the labeling of the figures is handwritten, i.e., Fig. 1, Fig. 2, etc.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing

should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

5. Claims 33, 45, 52, and 58 are objected to because of the following informalities: bacterial names should be in italics. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 62 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to the "use" according to claim 62. It is unclear what exactly if the "use" of claim 62.

8. Claims 31-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 31 recites a method for treating or preventing a disease comprising administering to a patient "in which thereof" a therapeutically effective amount of a polypeptide.

It is unclear what is meant by "in which thereof". Claims 32-39 depend from the claim, but do not clarify the issue.

9. Claims 31-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for DMBT1 identification and purification, production of DMBT1 knockout mice and *in vitro* binding studies, does not reasonably provide enablement for treatment or prevention of all diseases caused by all agents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention – methods of treating or preventing a disease caused by an agent possessing $\geq$1 accessible sulphate and/or $\geq$1 accessible phosphate group comprising administering to a patient a therapeutically effective amount of a polypeptide comprising the

sequence of SEQ ID NO:1, or a functional fragment or derivative thereof, or of a nucleic acid comprising the sequence of SEQ ID NO:2, or a functional fragment or derivative thereof.

The state of the prior art as evidenced by applicants specification, page 2, lines 7-21, indicates that DMBT1 (SEQ ID NO:1) is a salivary agglutinin and is known to interact with bacterial and viral pathogens (Prakobphol et al, *J. Biol. Chem.*, 275:39860-39866, 2000).

However, there is a lack of predictability in the art that administration of DMBT1 can treat or prevent all diseases caused by all agents.

The amount of direction or guidance present in the instant specification is insufficient support for the extremely broad scope of the instant claims. While the specification hypothesizes that DMBT1 may treat and prevent diseases, the only working examples are directed to identification, purification and *in vitro* binding of DMBT1 and the production of DMBT1 knockout mice. There are no working examples of treatment by administration of DMBT1.

Thus, the instant claims constitute merely an invitation to experiment without a reasonable expectation of success.

10. Claims 40-48 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: method of identification.

The claims merely state that an agent in a sample will be incubated with a polypeptide/functional derivative/fragment. There is no step(s) which show how one identifies said agent.

11. Claims 49-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a method for diagnosing the susceptibility of an individual to an agent by detecting in a sample (source not indicated and therefor not restricted to said individual) a polypeptide "comprising" the sequence of SEQ ID NO:1 a functional fragment or derivative thereof, or a nucleic acid "comprising" the sequence of SEQ ID NO:2, or a functional fragment or derivative thereof, wherein "a shortened polypeptide or a shortened nucleic acid as compared to the full-length polypeptide or nucleic acid is indicative of an increased susceptibility".

Because of the open language, i.e., a polypeptide "comprising" a known sequence or a nucleic acid "comprising" a known sequence, permits any number of unknown amino acid or nucleic acid residues on either end of the known sequences. Thus, the actual identity and therefor the length of the polypeptide or polynucleotide in these unknown regions is undetermined. Therefor, it is unclear how one determines if you actually have "a shortened polypeptide or a shortened nucleic acid as compared to the full-length polypeptide or nucleic acid" and thus, how one determines if the result is actually indicative of an increase susceptibility.

12. Claims 55-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a method for determining the effective amount of a pharmaceutical comprising an agent by detecting in a sample (source not indicated and therefor

not restricted to said individual) a polypeptide "comprising" the sequence of SEQ ID NO:1 a functional fragment or derivative thereof, or a nucleic acid "comprising" the sequence of SEQ ID NO:2, or a functional fragment or derivative thereof, wherein "a shortened polypeptide or a shortened nucleic acid as compared to the full-length polypeptide or nucleic acid is indicative for a lower effective amount".

Because of the open language, i.e., a polypeptide "comprising" a known sequence or a nucleic acid "comprising" a known sequence, permits any number of unknown amino acid or nucleic acid residues on either end of the known sequences. Thus, the actual identity and therefor the length of the polypeptide or polynucleotide in these unknown regions is undetermined. Therefor, it is unclear how one determines if you actually have "a shortened polypeptide or a shortened nucleic acid as compared to the full-length polypeptide or nucleic acid" and thus, how one determines if the result is actually indicative for a lower effective amount.

13. Claims 61-66 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for DMBT1 identification and purification, production of DMBT1 knockout mice and *in vitro* binding studies, does not reasonably provide enablement for treatment or prevention of all diseases caused by an agent possessing $\geq$1 accessible sulphate and/or $\geq$1 accessible phosphate group by administration of a therapeutically effective amount of $\geq$1 amino acid motif comprising 11 contiguous amino acids derived from a polypeptide comprising SEQ ID NO:1 or of a nucleic acid encoding said amino acid motif. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention - treatment or prevention of all diseases caused by an agent possessing $\geq$1 accessible sulphate and/or $\geq$1 accessible phosphate group by administration of a therapeutically effective amount of $\geq$1 amino acid motif comprising 11 contiguous amino acids derived from a polypeptide comprising SEQ ID NO:1 or of a nucleic acid encoding said amino acid motif.

The state of the prior art as evidenced by applicants specification, page 2, lines 7-21, indicates that DMBT1 (SEQ ID NO:1) is a salivary agglutinin and is known to interact with bacterial and viral pathogens (Prakobphol et al, *J. Biol. Chem.*, 275:39860-39866, 2000).

However, there is a lack of predictability in the art that administration of subunits (motifs) of DMBT1 can treat or prevent all diseases caused by all agents.

The amount of direction or guidance present in the instant specification is insufficient support for the extremely broad scope of the instant claims. While the specification hypothesizes that DMBT1 may treat and prevent diseases, the only working examples are directed to identification, purification and *in vitro* binding of DMBT1 and the production of DMBT1 knockout mice. There are no working examples of treatment by administration of subunits of DMBT1.

Thus, the instant claims constitute merely an invitation to experiment without a reasonable expectation of success.

Conclusion

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

April 24, 2009